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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/757,346

01/14/2004

Heinrich Kladders

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3492

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EXAMINER

MATTER, KRISTEN CLARETTE

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

11/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/757,346

Applicant(s)

KLADDERS ET AL.

Examiner

Kristen C. Matter

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Action is in response to the Request for Continued Examination submitted on 10/10/2007. No claims were amended, but additional remarks requesting reconsideration were considered by the examiner. Currently, claims 1-10 are pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. (US 5,947,118) in view of Datta et al. (US 5,871,010) and further in view of Bartels et al. (US 5,472,143).

As to claims 1 and 5, Hochrainer et al. disclose an inhaler for the administration of a pharmaceutical composition comprising a mouthpiece (12), an air channel opening into the mouthpiece and a chamber (9) with an air inlet channel wherein the inhaler is capable of receiving a capsule with a composition (see Figure 6). Hochrainer et al. does not disclose at least part of the inner surface of the mouthpiece and/or of the air channel and/or optionally the chamber contains elevations and/or depressions with a height/depth of from 0.1 to 100 microns. However, Datta et al. teach an inhaler apparatus with a modified surface for enhanced release of dry powders. Datta et al. disclose the surface of the substrate and the mouthpiece as having elevations and depressions with a depth of one micron to about 2.5 microns (column 2, lines 15-

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44), which meets the claimed range of 0.1 to 100 microns. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Hochrainer et al. with the depressions taught by Datta et al. in order to decrease the area of contact between the selected medicaments so that medicament particles do not stick to the inside surface of the mouthpiece. In addition, the only difference between the depressions of Datta et al. and the instant application is the shape (i.e., "egg-carton" versus parallel grooves). Absent a critical teaching and/or a showing of unexpected results from making the depressions egg-carton shaped, Examiner contends it is an obvious design consideration to one of ordinary skill in the art to make the depressions grooves or egg-carton shaped as a matter of manufacturing preference. Furthermore, because the grooves of Datta et al. are provided to minimize the area of contact in order to maximize the release of medicament (column 2, lines 25-30 and column 7, lines 55-60), it appears as though the modified device would perform equally well with egg-carton depressions as opposed to parallel grooves. See also *In re Dailey*, 357 F.2nd 669, 149 USPQ 47 (CCPA 1966), in which the court upheld that changes in shape without a change in function do not patentably distinguish a claimed invention over the prior art. The modified Hochrainer and Datta et al. reference is silent as to the process for forming the elevations/depressions. Bartels et al. disclose an atomizing nozzle for use in an inhaler in which the depressions forming the nozzle outlets are formed from well-known microforming techniques including chemical etching, laser, photo-resist, or other engraving techniques (column 4, lines 10-25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used chemical etching (a microtechnology and subtractive treatment), for example, to produce the depressions in the modified device of Hochrainer et al.

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and Datta et al. in order to produce readily reproducible and accurate depressions in the mouthpiece on a micro-scale.

As for claim 2, Datta et al. is silent as to the percentage of the interior surfaces having depressions. However, it would have been an obvious design consideration to one of ordinary skill in the art at the time the invention was made to have used microtechnology to produce depressions over at least 20% of the inner surfaces in order to deliver a maximum amount of medicament to the user without having the particles stick to the inside surfaces of the inhaler.

As for claim 3, Datta et al. disclose the elevations and depressions are separated by spacings of 2 microns, which reads inside the range from 0.1 to 200 microns.

As for claim 4, Datta et al. has taught an inhaler with inner surfaces being made with polycarbonate (column 7, line 65), for example, which is one of the claimed materials.

As for claims 6 and 7, Hochrainer et al. inherently disclose a Bernoulli inhaler. In addition, the applicant has admitted that Bernoulli inhalers are prior art (paragraph 3, lines 4-7). Hochrainer et al. disclose the inhaler comprising a capsule chamber (9), which is connected to the air channel opening in the mouthpiece.

In regards to claims 9 and 10, Hochrainer et al. disclose the inhaler as having a cutting device, which is fitted with at least two sharp spikes, the spikes are capable of being inserted through openings into the capsule chamber (column 3, lines 5-9). Hochrainer et al. continue to disclose an inhaler comprising a cup-shaped lower part 6 open at the top, a plate (8) that covers the opening of the lower part (6) and perpendicularly to which is formed the capsule chamber, a button (10) movable counter to a spring on the capsule chamber, comprising two sharp spikes for opening the capsule, an upper part (13) with the mouthpiece (12) and the air channel which

connects the mouthpiece (12) to the capsule chamber (9) so as to be able to convey a powder or liquid or aerosol, and a lid, these elements being joined together by a common hinge element such that they can be moved back and forth relative to one another (column 3, lines 15-18).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hochrainer et al. and Datta et al. and Bartels et al. and further in view of Kladders (US 4,889,114). The modified Hochrainer et al. reference has disclosed everything except the capsule chamber as having a diameter 1.1 to 2.5 times the capsule diameter and a length 1.02 to 2 times the length of the capsule. However, Hochrainer et al. has taught that the capsule chamber needs to have a diameter large enough to hold the capsule (column 1, lines 19-21). In addition, Kladders discloses a similar powder inhaler with a capsule chamber (6) with a diameter 1.1 to 2.5 times the capsule diameter and a length 1.03 to 2 times the length of the capsule (column 2, lines 10-19). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the device of Hochrainer et al., Datta et al., and Bartels et al. with the capsule chamber diameter and length as taught by Kladders so that the capsule fits in the chamber in order to be more effective during delivery for inhalation.

Response to Arguments

Applicant's arguments filed 10/9/2007 have been fully considered but they are not persuasive.

In response to applicant's arguments that the Datta et al. reference teaches away from increasing the surface area of contact of medicament and the surfaces of the inhaler, examiner

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agrees that the purpose of the Datta et al. elevations/depressions is indeed to minimize the contact area, as is evident from column 5, lines 29-30, for example. However, examiner disagrees that "egg-carton" shaped elevations/depressions would increase the surface area of contact as compared to parallel grooves, for example, because it seems as though the egg-carton shaped depressions would involve removing more material from the surface to produce the depressions in an egg-carton shape, thereby actually further reducing the contact area of the medicament with the surfaces of the inhaler as compared to parallel grooves. In addition, examiner points to column 5, lines 42-43, in which Datta et al. explicitly disclose the elevations/depressions may be curved or circular as opposed to simply linear. This may either be taken as a disclosure of "egg-carton" shaped elevations/depressions or at a minimum, as evidence that one of ordinary skill in the art would expect the device to perform equally well with the egg-carton shaped elevations/depressions, and as stated above, a mere change in shape does not patentably distinguish the invention from the prior art. For the above reasons, examiner believes a proper prima facie case of obviousness has been presented.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, motivation to use egg-carton shaped elevations/depressions is found in the Datta et al. reference because Datta et al. discloses various


shaped for the elevations/depressions (including circular) and using egg-carton shaped elevations/depressions would still reduce the area of contact of the medicament with the inside surface of the inhaler.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen C. Matter whose telephone number is (571) 272-5270. The examiner can normally be reached on Monday - Friday 9-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Kristen C. Matter
Examiner
Art Unit 3771


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11/15/07